

REMARKS

Applicants have received and reviewed the Office Action dated March 26, 2010. By way of response, Applicants present the following remarks. Applicants have amended claims 37-40 and present new claims 41 and 42. No new matter has been added. Claims 19-42 are pending, although claims 19-36, 38 and 40 have been withdrawn.

Applicants submit that the amended and newly presented claims are supported by the specification as filed. The term "wherein a reduced expression of SIAH-2 and DEME-6 in said primary tumour, as compared to a reference sample, is indicative of a Cluster 1 expression pattern; and wherein elevated expression of SIAH-2 and DEME-6 in said primary tumor, as compared to a reference sample, is indicative of a Cluster 2 expression pattern" was introduced in claims 37 and 39. Basis for this amendment is present at least at [0052] on page 4 of US20080113345. Applicants further submit that it is clear from the replacement Figure 2, that the expression of SIAH-2 and DEME-6 is downregulated in a Custer I expression pattern (indicated as green in Figure 2), while the expression of SIAH-2 and DEME-6 is upregulated in a Custer II expression pattern (indicated as red in Figure 2).

New claims 41 and 42 were added. Claim 41 is directed to the method according to claim 37, wherein said reference sample comprises a cell line pool of cell lines from different tissue origins. Claim 42 is directed to the method according to claim 39, wherein said reference sample comprises a cell line pool of cell lines from different tissue origins. Basis for claims 41 and 42 is present in [0052] on page 4 of US20080113345.

For the reasons presented below, Applicants respectfully submit that the amended and newly presented claims are in condition for allowance, and notification to that effect is earnestly solicited.

Restriction and Species Election Requirements

Applicants acknowledge that the restriction and species election requirements have been made final. Applicants respectfully request rejoinder of at least claims 38 and/or 40 upon allowance of a generic claim.

Oath/Declaration

The Examiner asserted that the oath or declaration is defective, as it does not list the mailing address of each inventor. Applicants are in the process of obtaining the required information and will submit an Application Data Sheet within the next couple of weeks.

Drawings

The objection to the drawings has been addressed in an Amendment including color replacement drawings and a petition to accept color drawings submitted eventdate herewith by first class mail.

Specification

The specification was objected to for containing an embedded hyperlink and/or other form of browser-executable code. The specification has been amended as suggested by the Examiner to address this objection.

Claim Objections

The Examiner objected to claim 39 for a minor informality. Amended claim 39 does not include the informality objected to in the Office Action.

Accordingly, Applicants respectfully request withdrawal of this objection.

Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 37 and 39 under 35 U.S.C. § 112, second paragraph. The Examiner objected to certain terms employed in these claims. Applicants respectfully traverse this rejection.

The Office Action objected to the recitation of the term "Table 1" in claims 37 and 39. Each of claims 37 and 39 now recites "Table 2", which Table refers to the elected markers.

The Office Action objected to the terms "Cluster 1" and "Cluster 2" in claims 37 and 39 due to the lack of color in Figure 2. In an amendment submitted eventdate herewith by first class mail, Applicants provided a color version of Figure 2.

The Office Action objected to the term "correlating" in claims 37 and 39. Amended claims 37 and 39 do not include this term.

Accordingly, Applicants respectfully submit that the amended and newly presented claims fully comply with § 112, second paragraph, and withdrawal of this rejection is earnestly solicited.

Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 37 and 39 under 35 U.S.C. 112, first paragraph, in an enablement rejection. Applicants respectfully traverse this rejection.

The Office Action asserts that the claims are not enabled because Figure 2 lacks color. In an amendment submitted even date herewith by first class mail, Applicants provided a color version of Figure 2.

Accordingly, Applicants respectfully submit that the amended and newly presented claims fully comply with § 112, first paragraph, and withdrawal of this rejection is earnestly solicited.

Further, Applicants respectfully submit that hormonal anti-estrogen therapy works against estrogen receptor-positive breast cancer. In fact, the presence of estrogen receptor is one of the criteria that are used for prescribing anti-estrogen therapy. Hence, a prediction of the outcome of anti-estrogen therapy according to claims 37 and 39 is informative for estrogen receptor-positive breast cancer patients.

As is indicated in the introduction, about 50% of estrogen receptor-positive breast cancers will not respond to anti-estrogen therapy. The expression levels of the marker genes, including SIAH-2 and DEME-6, was found to differentiate between estrogen receptor-positive breast cancers that did respond to anti-estrogen therapy, versus estrogen receptor-positive breast cancers that did not respond to anti-estrogen therapy (see, for example, [0046] on page 3, and [0046] on page 4 of US20080113345).

Hence, the differential expression of SIAH-2 and DEME-6 in estrogen receptor-positive breast cancers as compared to estrogen receptor-negative breast cancers is not relevant for the present invention.

Rather, the present invention for the first time provides markers that allow to discriminate between estrogen receptor-positive breast cancer patients that might benefit from anti-estrogen

therapy versus estrogen receptor-positive breast cancer patients that are not likely to benefit from anti-estrogen therapy.

Such differentiation was not possible before the present invention, nor could this be derived from, for example, one or both of U.S. Patent Nos. 7,531,300 or 7,504,222, which are referred to in this rejection.

Accordingly, Applicants respectfully submit that the amended and newly presented claims fully comply with § 112, first paragraph, and withdrawal of this rejection is earnestly solicited.

Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

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Date:

27 Sept '10

MTS:kf


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